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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,792	02/06/2004	Thomas W. Dubensky JR.	ANZ-1200-UT2	8458
35938 7590 05/04/2009 BioTechnology Law Group 12707 High Bluff Drive Suite 200 San Diego, CA 92130-2037				
EXAMINER				
GRASER, JENNIFER E				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
05/04/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DOCKETING@BIOTECHNOLOGYLAWGROUP.COM

### Office Action Summary

**Application No.**

10/773,792

**Applicant(s)**

DUBENSKY ET AL.

**Examiner**

Jennifer E. Graser

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22,38-41,76,77,81-83 and 90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,38-41,76,77,81-83 and 90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/5/09&2/5/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 2/5/09 is made. Claims 22, 38-41, 76, 77, 81-83 and 90 are currently pending.

#### ***Rejections which have been withdrawn:***

1. The obviousness-type double patenting as being unpatentable over claims 1-66, 69-72, 74-76, 88-93, 102-109, 11-116, 118-128 of copending Application No. 10/883,599 has been withdrawn. The amendment of the co-pending claims has obviated this rejection.

The former rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Appelberg et al (Infect. Immun. Feb. 2000. 68(2): 912-914) has been withdrawn. Appelberg et al. does not suggest deleting *both* actA and inlB in the context of retaining inlA. Appelberg et al. does not delete inlB in isolation; Appelberg et al. deletes the entire inlA/B operon. Thus, while one of skill in the art might arguably have been motivated from the Appelberg et al. to produce a mutant deficient in both actA and inlA/B (a point Applicants do not concede), one would not have been motivated to produce a mutant deficient in actA and inlB while leaving inlA intact. The specification has shown unexpected results through the retention of the inlA gene.

The amendments to the claims have obviated the former rejections under 35 USC 112, 2<sup>nd</sup> paragraph and 35 USC 112, first paragraph enablement rejection.

***Double Patenting***

2. Claims 22, 38-41, 76, 77, 81-83 and 90 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 21, 83-87, 97-107, 109-118, 128-138, 140-149 and 150-189 of copending Application No. 10/773,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims encompass methods which use any bacterium which has been attenuated for proliferation by reaction with a nucleic acid targeted compound that reacts with the nucleic acid (see instant claims 25 and 26). The phenotypes 'attenuated for entry into non-phagocytic cells and for cell-to-cell spread' are forms of proliferation and are, therefore, encompassed in the language of the claims from 10/773,618. Co-pending claims 13 and 16 recite that the microbe is a bacterium, more specifically *L.monocytogenes* and co-pending claim 18 encompasses mutations in both the *actA* and *inlB* genes. Co-pending claims 113 and 120 recite the same tumor antigens as the heterologous antigens recited in instant claim 35. Both applications teach the use of these bacterium in methods inducing an immune response to antigen and methods for treating or preventing a disease in a host. Accordingly, since the scope of the instant claims is encompassed by the Genus recited in 10/773,618 the scope of the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112-New Matter***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22, 38-41, 76, 77, 81-83 and 90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Written support could not be found for the limitation "a functional genomic inlA gene whereby the bacterium expresses InlA protein" as recited in newly amended claim 22. In paragraph [0106] on page 26 it is recited that the mutant Listeria may comprise 'at least one mutation in the inlA gene'. Support could not be found for the underscored limitation set forth above. Applicant must point to specific written support by page and line number or remove it from the claim.

Written support could not be found for the limitation "A method of expressing a non-Listerial polypeptide in a host" as recited in newly amended claim 40. Note: this claim was amended from a 'method of treating a disease' to a 'method of expressing a non-Listerial polypeptide in a host'. This method was not previously examined. Applicant must point to written support by page and line number or remove it from the claim. Accordingly, written support could not be found for dependent claims 76, 77, 81, 82 and 90 which are drawn to how to select a host to use in this method, e.g., [t]he method of claim 40, wherein the host is selected on the basis of a need for protection

against a disease in the host". Written support could not be found for these limitations in the original claims or specification. Applicant must point to specific written support by page and line number or remove these limitations from the claim.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1645

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/  
Primary Examiner, Art Unit 1645

**4/27/09**